CLAIMS

1. An optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, serum albumin and a pharmaceutically acceptable vehicle, wherein the composition comprises no more than 10% organic solvent and has a pH of about 3.0 to about 4.8.

2. The composition of claim 1, wherein the serum albumin is undefatted.

3. The composition of claim 1, wherein the composition has been lyophilized or lyophilized and then reconstituted from the lyophilized formulation.

4. An optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, defatted serum albumin and a pharmaceutically acceptable vehicle, wherein the composition comprises about 10% or less organic solvent.

5. The composition as claimed in any one of 1 to 4, wherein at least 70% of the paclitaxel or derivative thereof introduced into the composition is bound to the serum albumin.

6. The composition as claimed in any one of claims 1 to 4, wherein at least 80% of the paclitaxel or derivative thereof into the composition is bound to the serum albumin.

7. The composition as claimed in any one of claims 1 to 4, wherein at least 85% of the paclitaxel or derivative thereof into the composition is bound to the serum albumin.

8. The composition as claimed in any one of claims 1 to 4, wherein at least 90% of the paclitaxel or derivative thereof into the composition is bound to the serum albumin.

9. The composition as claimed in any one of claims 1 to 8, wherein the ratio of paclitaxel or derivative thereof to albumin is at least about 1:5.

10. The composition as claimed in claim 9, wherein the ratio of paclitaxel or derivative thereof to albumin is greater than 1:4.

11. The composition of claim 1, wherein the ratio of paclitaxel or derivative thereof to albumin is at least about 1:4.

12. The composition of claim 1, wherein the ratio of paclitaxel or derivative thereof to albumin is at least about 1:2.

13. The composition of claim 1, wherein the ratio of paclitaxel or derivative thereof to albumin is at least about 1:1.

14. The composition of claim 1, wherein the ratio of paclitaxel or derivative thereof to albumin is at least about 1:1 to about 2:1.

15. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 25 μg/ml.

16. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 50 μg/ml

17. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 100 μg/ml.

18. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 200 μg/ml.

19. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 300 μg/ml.

20. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 400 μg/ml.

21. The composition as claimed in any one of claims 9 to 14, wherein the concentration of paclitaxel is greater than about 500 μg/ml.

22. The composition as claimed in any of claims 1 to 21, wherein the concentration of organic solvent is about 1 to about 10% v/v.

23. The composition of claim 22, wherein the concentration of organic solvent is about 2 to about 8% v/v.

24. The composition of claim 23, wherein the concentration of organic solvent is about 4 to about 6% v/v.

25. The composition of claim 3, wherein the composition is essentially free of organic solvent.

26. The composition as claimed in any of claims 1 to 24, wherein the organic solvent is alcohol.

27. The composition of claim 26, wherein the alcohol is ethanol.

28. The composition as claimed in any of claims 1 to 27, wherein the pH is about 3.0 to about 4.8.

29. The composition of claim 28, wherein the pH is about 4.0 or less.

30. The composition of claim 29, wherein the pH is less than about 4.0.

31. The composition of claim 30, wherein the pH is about 3.4 to about 3.8.

32. The composition of claim 1, wherein the serum albumin is at least about 80% to about 90% monomeric.

33. A lyophilized preparation of an optically clear, pharmaceutically acceptable aqueous composition comprising paclitaxel or a derivative thereof, serum albumin and a pharmaceutically acceptable vehicle, wherein the ratio of paclitaxel or derivative thereof to albumin is about 1:4, and wherein the composition comprises less than 10% organic solvent and has a pH of about 3.0 to about 4.8 upon reconstitution, and wherein at least about 70% of the paclitaxel introduced into the composition is bound to the serum albumin and wherein the paclitaxel concentration in the composition is at least 50 μg/ml.

34. A method of treatment, comprising administering to a patient in a pharmaceutically acceptable form a therapeutically effective amount of a composition as claimed in any of claims 1 to 33.

35. A method of making a composition as claimed in any of claims 1 to 33, comprising the steps of: preparing a solution of the paclitaxel or a derivative thereof; preparing a solution of serum albumin; and slowly combining the solutions, and optionally lyophilizing or optionally lyophilizing and reconstituting the combined solutions.

36. The method of claim 35, wherein the ratio of paclitaxel or derivative thereof to albumin is about 1:1, and the solutions are combined at a temperature below room temperature.

37. The method of claim 35, wherein the ratio of paclitaxel or derivative thereof to albumin is about 1:1, and the solutions are combined at a temperature of about 2 to about 8°C.

38. The method of claim 35, wherein the ratio of paclitaxel or derivative thereof to albumin is about 1:1, and solutions are combined at a temperature of about 4°C.

39. A composition as claimed in any of claims 1 to 33, wherein the desired dose can be administered in a period of less than 3 hours.

40. A composition as claimed in any of claims 1 to 33, wherein the desired dose can be administered in a period of less than 2 hours.

41. The method as claimed in any of claims 35 to 38, wherein the solution of paclitaxel is added dropwise at a controlled rate.

42. The method as claimed in any of claims 35 to 38, wherein the solution of paclitaxel is added at a rate of about 1 ml/minute or slower and the drop size is 8 to 20 μl.

43. A method of treatment, comprising administering to a patient a therapeutically effective amount of an optically clear, pharmaceutically acceptable aqueous composition comprising a hydrophobic drug, a globulin and a pharmaceutically acceptable vehicle, where the drug and the globulin are present in at least about approximately a 1:2 molar ratio.

44. A composition comprising a therapeutically effective amount of an optically clear, pharmaceutically acceptable, aqueous composition comprising a hydrophobic drug, a globulin, and a physiologically acceptable vehicle wherein the drug and globulin are present at about a 1:2 molar ratio and the pH is at or below the pI of the globulin.

45. A method of making an optically clear, pharmaceutically acceptable, aqueous composition of a hydrophobic drug, a globulin, and a physiologically acceptable vehicle, comprising the steps of: preparing a solution of the globulin; preparing a solution of drug; and slowly adding the drug solution to the globulin solution, where the globulin solution is at or below the pI of the globulin.